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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,629	10/19/1999	JAY M. SHORT	DIVER1260-3	4408

7590

02/15/2002

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EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/15/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/421,629

Applicant(s)

Short et al.

Examiner

Nashaat T. Nashed

Art Unit

1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jan 3, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-47 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

The application has been amended as requested in the communication filed January 3, 2002. Accordingly, claims 32, 33, and 43-47 have been entered and under consideration in this Office action.

The attempt to incorporate subject matter into this application by reference to serial number 09/089,789, 09/034,724, and 08/665,565 is improper because it amounts to the introduction of new subject matter to the specification after the filing date of October 19, 1999.

The amended continuity data filed January 3, 2002 is objected to because it is confusing for the following reasons:

- (i) The continuity data states that the instant application is a continuation of 08/657,409 ('409), but there is no copendency between the instant application, filed October 19, 1999, and the '409 application because the '409 application was issued as U. S. patent 5,958,672 on September 28, 1999. It is presumed that the applicant intended to say "This application is a continuation of serial number 08/988,224 filed December 10, 1997, now U. S. patent, 6,280,926, which is a continuation of serial number 08/657,409, now U. S. patent .....".
- (ii) The instant application can not possibly be a continuation or divisional of serial number 08/988,224 or 08/657,409 and be a continuation of serial number 09/089,789 in the same time. Serial number 09/089,789 is a different application from those of the instant application, 08/988,224 and 08/657,409, and has no common ancestor with serial number 08/988,224. In the filing of the instant application, Applicants indicated that this application is identical to serial number 08/988,224.

Correction of the continuity data is required.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it contains improper claimed priority information. Specifically, it claims priority to serial number 09/089,789 filed June 3, 1998, which is a CIP of serial number 09/034,724, filed March 4, 1998, which is a CIP of 08/665,565 filed June 18, 1996.

The terminal disclaimer filed on December 6, 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U. S. patent, 5,958,672; 6,168,919; 6,174,673; 6,280, 926; and any patent which may mature from copending application serial number 09/467,740 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 32-47 drawn to gene expression library which contains partial or complete metabolic pathway is not enabled in the parent applications serial numbers 08/503,606 and 08/568,994 from which serial number 08/988,224 is a continuation in part. The instant application is a continuation of 08/988,224 and not a divisional application. Since claims 32-33, and 36-47 are not limited to specified enzymatic activities, the claims encompass gene clusters of metabolic pathway which have the priority date of June 3, 1996.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-47 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the previous Office action, paper number 12.

In response to the above rejections applicants argue that gene clusters encoding enzymes are merely exemplary of gene clusters encoding metabolic pathway in general. Also, they argue that an additional claimed priority from pending application 09/089,789, 09/034,724, and 08/665,565.

Applicants' arguments filed 1/3/01 have been fully considered but they are not deemed to be persuasive. A single enzyme does not define neither a metabolic pathway or gene clusters. While it is possible to identify a gene encoding a single enzyme by the claimed method, the identification of a metabolic pathway or gene cluster is a different matter, specifically when the organism from which the single enzyme is unknown. Claiming a new priority to applications 09/089,789, 09/034,724, and 08/665,565 and incorporating them by reference amount to introducing a new matter to the specification after the filing date, i. e., 10/19/99, also see the discussion above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) The phrase "in the normalized library" in claim 32, last line, renders the claim indefinite. The phrase is not defined by the specification and one of ordinary skill in the art would not know the metes and bound of that phrase.
- (b) claims 33-43 are included in this rejection because they are dependent on rejected claims and do not correct the deficiencies of the claim from which they depend.

No claim is allowed.

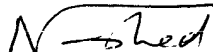
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner

The attempt to incorporate subject matter into this application by reference to serial number 09/089,789, 09/034,724, and 08/665,565 is improper because it amounts to the introduction of new subject matter to the specification after the filing date of October 19, 1999.

The proposed amendment in the after-final communication to continuity data filed June 3, 2002, which has not been entered into the record, would obviate the objections to the continuity data.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-47 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the previous Office actions, paper numbers 6 and 12.

In response to the above rejections applicants continue to argue that gene clusters encoding enzymes are merely exemplary of gene clusters encoding metabolic pathway in general.

Applicants' arguments filed 6/3/02 have been fully considered but they are not deemed to be persuasive. A single enzyme does not define neither a metabolic pathway or gene clusters. While it is possible to identify a gene encoding a single enzyme by the claimed method, the identification of a metabolic pathway, gene cluster or part thereof is a different matter, specifically when the organism from which the single enzyme is unknown. Identifying a vector containing the expression construct that produces the bioactivity or biomolecule of interest encoded by the cDNA or genomic DNA fragment in the library is not enabled in the specification. Applicant is reminded that the claimed invention has to be enabled in such a way that one of ordinary skill in the art would be able to carry out the claimed invention without undue experimentation. No hybridization probes are taught in the specification which would allow the ordinary skill in the art to identify a vector or nucleic acid encoding for a desired activity. The specification fails to teach any method of any kind for the identification of gene clusters or metabolic pathway. Thus, the claims remain rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) The phrase "in the normalized library" in claim 32, last line, renders the claim indefinite. The phrase is not defined by the specification and one of ordinary skill in the art would not know the metes and bound of that phrase.
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No claim is allowed.

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Nashaat T. Nashed, Ph. D.  
Primary Examiner